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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,843	04/25/2001	Jurgen Bode	BOET 0130 PUS	6703

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/841,843	BODE ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 February 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-4 and 6-10*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *Interview summary attached*

Joe Woitach
AU1632

Continuation of 3. Applicant's reply has overcome the following rejection(s):
The amendment to claim 10 obviates that rejection made under 35 USC 112, 1st paragraph.

Continuation of 5. does NOT place the application in condition for allowance because:
Initially, it is noted that the amendment would be entered and that the amendments to claim 10 obviated the rejeciton under 35 USC 112, first paragraph (and to claim 6 would obviate any potential rejection under the same statute on how to use) .

With respect to the art rejections, it appears that arguments set forth in the after final amendment focus primarily on the differences between the examples in the instant specification and those of Schlake et al. Examiner acknowledges Applicants arguments as supporte by the declaration of Nordheim, however while Schlake et al. do not reduce to practice each of these limitations, they do provide the guidance that anticipate each of the limitations set forth in the claims. Further, Applciants arguments that the system would not work or that it is not predictable in ES cells is not found persuasive because similar systems have already been successfully used in ES cells and the Flp/frt systemhas been demonstrated to work in other mammalian cells (as demonstrated by Schlake et al.) and by itself is functional even in vitro indicating the cell type would not be important or limiting for use of the vector system (again taught in Schlake et al.). Schlake et al. provide the teaching of a vector system for site directed homologous recombination of a sequence of interest into the genome of a cell of any cell and is the same vector system that is presented in the instant specification. Morevoer, given the general state of the art for the use of embryonic stem cells at the time of filing there are multiple examples of similar systems such as the Cre/lox system, used in mouse ES cells giving a resonable expectation that the system would work in these cells. The choice and use of cell line that do not exhibit homologous recombination as do ES cells is not a teaching away by Schlake et al., but a demonstration of the stength of the system to work in any cell even ones that do not exhibit homologous recombination. Examiner notes the differences between the mutated frt sequences in both the specification and as taught by Schlake et al., however the instant claims encompass all these sequences and thus, the same breadth of the different results. Importantly, the instant claims would be subject to any limitation of using any of these sequences. Arguments that a particular frt sequences were reduced to preactice in the specification and primarily used in Schlake et al. are not persuasive because the instant claims encompass all frt sequences, and any difference among the sequences are inherent and encompassed by the instant claims, and not considered a teaching away from the claimed invention.

Examiner would agree that some of the specific examples in the specification regarding the use of specific frt sequences and % recombination do provide a basis of unexpected results based on the art of record, however none of the pending claims recite limitations representing these unexpected results.

For the reasons above and of record, the rejections made under 35 USC 102 and 103 are maintained. .